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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/875,994	06/08/2001	Bruno Biatry	208594US0	8350
22850	7590	04/07/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			YU, GINA C	
			ART UNIT	PAPER NUMBER
			1617	
DATE MAILED: 04/07/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/875,994

Applicant(s)

BIATRY, BRUNO

Examiner

Gina C. Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on January 21, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 and 26-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 and 26-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of appeal brief filed on January 21, 2004. The finality of the Office action dated July 29, 2003 is withdrawn in view of enablement and double patenting issues. Obviousness double patenting rejections are made. Claim rejections as indicated in the previous Office action dated July 29, 2003 are maintained. Claims 1-24 and 26-31 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-24 and 26-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for protecting skin, does not reasonably provide enablement for protecting "keratin materials". Similarly, the disclosure fails to enable for all "pollutions", although specification enables for protecting skin against carbon-14 radio labeled particles. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether any necessary experimentation is "undue" include, but are not limited to: the breadth of the claims; the nature of the invention; the state of the prior art, the level of one of ordinary skill; the level of predictability in the art; the amount of direction provided by the inventor; the existence of working examples, and the quantity of experimentation needed to make or use the

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invention based on the content of the disclosure. See In re Wands, 858 F.2d 731, 737, 8 U.S.P.Q. 2d 1400, 1404 (Fed. Cir. 1988).

In this case, applicants claim the method of protecting any type of “keratinous materials”. While keratin materials may include human nail and hair, or even synthetic keratin, applicants’ disclosure merely shows skin treatment compositions and the method of using the compositions. See spec. p. 14-17. Furthermore, claim 24 recites “reducing the desquamation of keratin materials and/or preventing an increase in sebum flow from a keratin material”. Human nails or hair would not undergo desquamation nor sebum flow. There is no guidance, working example, or reasonable predictability of the efficacy of the invention with respect to the keratin materials other than skin.

With regards to “pollutions”, examiner views that the term pollution may include contamination by either chemical or waste products, and not only the specific type of pollutant applicants used to demonstrate the efficacy of the invention. There is no guidance, working example, or reasonable predictability of the efficacy of the invention with respect to the all type of pollution other than carbon-14 radio labeled particles.

Applicants’ disclosure fails to enable the claimed method of protecting all keratin materials, as undue experimentation is necessary to determine the efficacy of the invention as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-23 and 26-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms “the harmful effects” in claim 1 and “the effects” in claim 23 render the claims vague and indefinite, as it is not clear what is considered “the harmful effects” or “the effects” of pollution. The metes and bound of the scope of the claim are not clear.

The remaining claims are rejected as depending on the indefinite base claims.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-24 and 26-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Ribier et al. (U.S. Pat. No. 6,071, 524) (“Ribier I”).

Ribier I discloses compositions for skin, where in an oily phase, stabilized by cubic gel particles formed of phytanetriol, is dispersed in an aqueous phase. See col. 1, line 7- col. 2, line 18. See Examples 6 and 7, which are directed to day creams for skin protection. The reference further discloses the specific limitations of instant claims 7-22, 27, and 30. See col. 3, line 9 – col. 9, line 19.

Topically applying a cosmetic is an inherent use of the composition. The claimed method is inherently practiced by any users of the Ribier I invention. Applicants’ assertion urban populations using the Ribier I invention would not desire the benefit of

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the composition claimed by applicants lacks evidentiary support and does not render the present invention novel.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1, 23, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Derwent Acc. No. 1986-321473 (English abstract of JP 61236737 A) ("Kuraray abstract" hereunder).

Kuraray abstract states, "[p]hytanetriol is known as useful cosmetic component with protective action for skin or hair." See Basic-Abstract.

While the reference does not specifically teach to use the effective amount to protect the skin from pollution penetration, given the general teaching of the protective function of phytanetriol, one having ordinary skill in the art at the time the invention was made would have discovered the workable amount of the active ingredient by routine experimentation.

2. Claims 2, 3, 5, 6, 15, 17-19, 21, and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuraray abstract as applied to claims 1, 23, and 24 above, and further in view of Ribier et al. (U.S. Pat. No. 5,834,018) ("Ribier II").

Kuraray abstract, discussed above, fails to teach the specific formulation of the composition.

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Ribier II teaches aqueous composition of cubic gel particles based on 0.1-15% by weight of phytanetriol. See abstract.

Given the general teaching that phytanetriol provides protective action for skin, a one having ordinary skill in the art at the time the invention was made would have been motivated to look for specific formulations comprising phytanetriol such as Ribier II and applied the prior art invention with the expectation that the Ribier invention would successfully protect the skin.

3. Claims 2-4, 26, 28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuraray abstract as applied to claims 1, 23, and 24 as above, and further in view of Murad (U.S. Pat. No. 6,207,694 B1).

Kuraray abstract, discussed above, fails to teach the specific formulation of the composition.

Murad teaches a composition for prevention and treatment of hair and scalp condition comprising phytanetriol. See abstract; Examples 2, 3, 5, and 7-9. The use of the composition encompasses reducing hair and scalp damages from exposure to pollution or overdrying. See instant claims 1, 23, and 24. See col. 5, lines 5 – 12; 9, lines 17 – 21. Examples 2, 3, 5, and 7-9 illustrate formulations comprising phytanetriol in the amount of 0.02 – 0.3 % by weight of the total composition. See instant claims 2 and 3. The formulas are also homogenous mixture of oil and aqueous phases. See instant claims 4, 26, and 29 are met. Examples 5, 7, and 8 are directed to scalp formulation. See instant claims 28 and 31.

Given the general teaching that phytanetriol provides protective action for hair or skin, a skilled artisan would have been motivated to look for the specific formulations such as the Murad invention, and to apply the composition with the expectation that it would successfully protect hair and scalp.

4. Claims 2-4, 26, and 29 are rejected under 35 U.S.C. § 103 (a) as unpatentable over Kuraray abstract as applied to claims 1, 23, and 24 above, and further in view of Bergmann (U.S. Pat. No. 6,110,450).

Kuraray abstract, discussed above, fails to teach the specific formulation of the composition.

Bergmann teaches composition for the treatment and protection of hair, comprising glycoceramide and phytanetriol. See abstract. The term "protection" in the reference includes the protection of the hair fibers from the harmful agents from unsuitable hair treatments (and inclement weather). See col. 1, line 17 - 26. Examiner views that applicant's broad definition of pollutant, which include gases or "heavy metals", encompasses the harmful metal agents from the hair treatment products. See spec. p. 2, lines 22-24. Examples 1 and 2 show emulsion formulations comprising phytanetriol in the amount of 0.1 % by weight of the total composition. See instant claims 2-4, 26, and 29.

Given the general teaching that phytanetriol provides protective action for hair or skin, one having ordinary skill in the art at the time the invention was made would have

been motivated to apply the Bergmann composition with the expectation that the Bergmann invention would successfully protect hair and scalp.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-24 and 26-31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of copending Application No. 09875993. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims are directed to method of protecting keratinous materials by topically applying a composition comprising cubic gel particles made of phytanetriol.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments with respect to claims 1-24 and 26-31 have been considered but are unpersuasive.

Applicants' argue that the Ribier I reference does not inherently anticipate the claimed invention. Applicants' argue that for pollution penetration limitation to occur, some geographic areas exist in which pollution generation is limited such that insufficient pollution exist to allow phytanetriol to limit penetration. Examiner finds the argument unpersuasive because the consumers of those areas would not be the person ***in need of*** the claimed protection. The prior art is thought to be used by population in general, including consumers in heavily polluted areas. Thus, it follows that the claimed invention is inherently anticipated by the users there, the persons who are ***in need of*** the claimed protection.

Applicants also argue that Ribier I does not provide any instruction regarding how to use or apply his composition. Examiner respectfully disagrees because applicants' claimed invention merely requires topically applying the composition comprising an effective amount of phytanetriol, which applicants disclose in the specification to be 0.001-20 % by weight and thereby reads on the prior art. Ribier I teaches that phytanetriol is used in the amount of 2.97 % by weight in both examples 6 and 7. Applicants' argument that the same amount of phytanetriol protects keratinous material only in applicants' invention and not in the prior art composition is thus illogical.

Regarding applicants' argument against the § 103 rejection, applicants assert that Kuraray fails to disclose "how or from what" such protection occurs. Applicants' argument is unpersuasive because how phytanetriol protects the keratinous material is not subject to patentability and would be the inherent function of the composition. See 35 U.S.C. § 101. Applicants' argument that the reference fails to teach from what

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protection is provided is also viewed unpersuasive. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In this case, the obviousness rejection is proper because because 1) the reference clearly provides the specific motivation to use the phytanetriol containing composition to protect hair and skin, and also because 2) the protection against pollutant penetration would naturally flow from practicing the prior art method. Applicants' remark that none of the secondary references, Ribier II, Bergman or Murad fails to teach or suggest using a "pollutant penetration limiting effective amount of phytanetriol" is erroneous because Ribier II clearly teaches using aqueous composition of cubic gel particles based on 0.1-15% by weight of phytanetriol, which meets the claim limitation.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-308-3951.

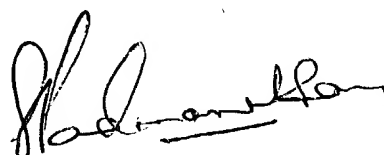
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-

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308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina C. Yu
Patent Examiner
April 5, 2004



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER